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APPLICATION FOR
UNITED STATES LETTER PATENT
SPECIFICATION

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TO ALL WHOM IT MAY CONCERN:

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Be it known that I, Konstantin L. Valtchev, a citizen of Canada, and resident of Canada, having a postal address of 233 Beecroft Road, Toronto, Ontario, Canada has invented new and useful "Vaginal Delineation and Occlusion Device," of which the following forms the specification.

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“VAGINAL DELINEATION AND OCCLUSION DEVICE”

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CROSS REFERENCE TO RELATED APPLICATIONS

Not applicable.

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STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

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REFERENCE TO MICROFICHE APPENDIX

Not applicable.

BACKGROUND OF THE INVENTION

Field of the Invention

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The present invention relates generally to a medical device. More particularly the present invention relates to a vaginal occlusion and self-adjusting delineation attachment for use in a uterine mobilizer.

Background Art

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Conventional hysterectomy surgical procedures typically involve one of four

approaches: vaginal hysterectomy, total abdominal hysterectomy (TAH), total laparoscopic hysterectomy (TLH), and laparoscopically assisted vaginal hysterectomy (LAVH). Vaginal, TLH and LAVH have become more popular among surgeons because these approaches are less invasive than TAH, with TLH being the least invasive approach. TLH is less invasive than LAVH because it avoids the trauma normally caused by the expansion induced to the vaginal area to permit access of the surgeons hands to the cervical area. Unless medical indications require TAH (such as in the case of tumor removal and the associated need to avoid cell spillage), vaginal, TLH and LAVH are usually viewed as more preferable because each is less invasive when compared to major abdominal surgery. Thus, TLH and LAVH approaches usually result in shorter hospitalization and recovery times.

Difficulties arise in TLH and LAVH, however, in identification when the vagina is not well delineated. Another technicality is leakage of carbon dioxide from the peritoneal cavity when the vagina is opened laparoscopically.

Another problem, not appropriately addressed in the prior art, is that human bodies vary considerably. Any vaginal insertion device for surgical procedures must, therefore, be adjustable. Such devices are, preferably, self-adjusting.

There is therefore a need for a vaginal delineation device, attachable to a uterine mobilizer, that also provides occlusion to the vagina to disallow leakage of carbon dioxide. There is a further need for a vaginal delineation and occluding device that is adjustable, and as self-adjusting as possible.

BRIEF SUMMARY OF THE INVENTION

An object of the present invention is to provide a vaginal delineator for use in female pelvic surgical procedures that attaches to a uterine mobilizer, such as the Valtchev Uterine Mobilizer, and is self adjusting to various lengths of cervixes and angles of fornices.

The present invention is a device that inserts and locks into a uterine mobilizer, the device comprises a ring that adjusts in angle. The ring is made to bear against the vaginal fornix, conforming to its angle and providing delineation of that part of the

vagina for identification thereof.

In a second embodiment, the ring is also self-adjusting as to distance from the uterine mobilizer, to accommodate varying lengths of the cervix. This is effected by pivotally mounting the ring onto four telescopic rods or legs, all spring loaded.

5 A third embodiment of the present invention is configured like a cup with a rigid ring, pivotally attached at the top of the cup. Again, the pivotal attachment provides accommodation for varying angles of the fornix.

Another object is to provide an occluder to prevent leakage of carbon dioxide from the peritoneal cavity when the vagina is opened laparoscopically. An enlarged portion of an extension at the base of the vaginal delineator, said extension being inserted into the uterine mobilizer, is made to receive a diaphragm made of an elastic material such as plastic, silicon, nylon, etc. The diaphragm obstructs the vaginal cavity toward the outside of the vaginal delineator, preventing leakage of carbon dioxide from the peritoneal cavity.

10 In the third embodiment of the invention, the cup is the occluding apparatus as well as the structure on which the variable-angle, rigid ring is mounted.

Other objects, advantages and novel features of the present invention will become apparent from the following detailed description of the invention when considered in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Fig. 1 is a side elevation view of a uterine mobilizer and a vaginal delineating and occluding device;

25 **Fig. 2a** is a first side elevation view of the vaginal delineating and occluding device;

Fig. 2b is a plan view from the top of the vaginal delineating and occluding device;

Fig. 2c is a second side elevation view of the vaginal delineating and occluding device;

30 **Fig. 2d** is a plan view from the bottom of the vaginal delineating and

occluding device;

Fig. 2e is a side elevation view of an arm for the vaginal delineating and occluding device;

Fig. 3a is a plan view of a diaphragm for the vaginal delineating and occluding device;

Fig. 3b is a top view of a diaphragm for the vaginal delineating and occluding device;

Fig. 4a is a plan view from the top of a second embodiment of the vaginal delineating and occluding device;

Fig. 4b is a side elevation view of the second embodiment of the vaginal delineating and occluding device;

Fig. 4c is a plan view from the bottom of the second embodiment of the vaginal delineating and occluding device;

Fig. 4d is a first side elevation view of an arm for the second embodiment vaginal delineating and occluding device;

Fig. 4e is a second side elevation view of an arm for the second embodiment vaginal delineating and occluding device;

Fig. 5a is a side elevation view of a third embodiment of the vaginal delineating and occluding device minus a solid ring to clearly show angles;

Fig. 5b is a cutaway side elevation view of a third embodiment of the vaginal delineating and occluding device;

Fig. 5c is a side elevation view of a third embodiment of the vaginal delineating and occluding device;

Fig. 5d is a plan view from the top of a third embodiment of the vaginal delineating and occluding device; and

Fig. 6 is a cutaway view of a female pelvis, the vaginal delineating and occluding device being mounted on a uterine mobilizer and inserted into the vagina.

DETAILED DESCRIPTION OF THE INVENTION

A first, preferred embodiment of a vaginal delineating and occluding device **100** is shown in **Fig. 1** along with a uterine mobilizer **110** as disclosed in U.S. Patent 5,562,679 which is hereby incorporated by reference. The vaginal delineating and occluding device **100** is attached to the head **120** of the uterine mobilizer **110**. The device shown in detail in **Figs. 2a–e** is a first embodiment of the vaginal delineating and occluding device **100** of the present invention. A base **205** has an extension **250** for insertion into the head **120** of the uterine mobilizer **110** and is locked therein. The proximal end **215** of the base **205** is for attaching obturators of various lengths. A solid metal ring **200** is attached to four legs **210**, **230**. The distal ends of a first pair of solid legs **210** are firmly affixed to the base **205**. The proximal ends of the legs **210** are pivotally attached to the ring **200** via pins **220** about which the ring **200** may pivot. The ring **200** is permitted to pivot about 20° in both directions from a plane perpendicular to a longitudinal axis of the base **205**. This pivoting permits the accommodation of various angles of the vaginal fornix **620** (see **Fig. 6**).

The first pair of legs **210** are preferably of a single piece, solid throughout.

The second pair of legs **230** are telescopic and comprise a plurality of parts as detailed in **Fig. 2e**. A distal end of a secure arm **255** is firmly affixed to the base **205**. The proximal end of the secure arm **255** engages a pin **280** to which an inner telescoping arm **265** is pivotally attached. The inner telescoping arm **265** slides into the distal end of an outer telescoping arm **260**. The outer telescoping arm **260** is pivotally attached to the ring **200** at its proximal end by a pin **270**. The outer telescoping arm **260** is a hollow tube to receive the proximal end of the inner telescoping arm **265**.

A diaphragm **225** of elastic material such as plastic, nylon, silicon, etc. is shown in **Figs. 3a** and **3b**. Its use is to obstruct the vagina for the prevention of carbon dioxide leakage from the peritoneal cavity when the vagina is opened laparoscopically. The diaphragm **225** has a hole **300** in its center through which an enlarged portion **275** of the base **205** of the vaginal delineating and occluding device **100** passes and helps secure the diaphragm **225**. When the distal end of the base **205** is inserted in the uterine mobilizer **110**, the diaphragm **225** is held securely between the base **205** and the

mobilizer 110. Various sizes of diaphragms 225 may be supplied to fit a variety of patients. About the circumference of the diaphragm 225 is an enlarged portion 310. A center annulus 320 is thicker than a center membrane 330.

5 A second embodiment of the vaginal delineating and occluding device 100 is shown in Figs. 4a–e. In this embodiment, all the legs 410 are made as the telescoping legs 230, described above. In addition, a spring 440 applies a force to separate the solid ring 200 away from the base 205. The spring 440 may bear directly on the secure arm 255 and the outer telescoping arm 260 as shown in Fig. 4d; or it may bear on the inner telescoping arm 265 and the solid ring 200 as shown in Fig. 4e. In this embodiment, the
10 location of the solid ring 200 relative to the base 205 is adjustable to accommodate various lengths of the cervix.

A third embodiment of the present invention is shown in Figs. 5a–d. Here, a cup 500 is illustrated the rim of which has a slope in two opposite directions, the slope having an angle, θ , where θ is about 15°. This cup 500 is attached in the same way into
15 the head 120 of the uterine mobilizer 110 via the extension 250. Pivotaly attached at the top if the cup 500 is a rigid ring 510, preferably constructed of a metallic material. The rigid ring 510 is pivotaly attached to pins 520 that permit the ring to tilt through the angle, θ , as far as the rim of the cup 500, again, about 15°. The view in Fig. 5a is intentionally without the ring 510 to show the angle θ . The ring 510 bears against the
20 fornix 620, while the cup 500 acts to occlude the vagina, replacing the diaphragm 225 of the previous embodiments.

The vaginal delineating and occluding device 100 of the first embodiment is shown in use in Fig. 6. The vaginal delineating and occluding device 100 is inserted into a vagina 610 using the uterine mobilizer 110 until the ring 200 of the vaginal delineating and occluding device 100 rests against the vaginal fornix 620.
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The above embodiments are the preferred embodiments, but this invention is not limited thereto. It is, therefore, apparent that many modifications and variations of the present invention are possible in light of the above teachings. It is, therefore, to be understood that within the scope of the appended claims, the invention may be practiced
30 otherwise than as specifically described.
